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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,758	01/04/2002	Fabienne Parker	ST98017 A	4189

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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/719,758

Applicant(s)

PARKER ET AL.

Examiner

Larry R. Helms

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,10 and 11 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 and 9 is/are allowed.
- 6) ☐ Claim(s) 1,3,7,8 and 13 is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 1, 3, 4, 7, 8 have been amended, claims 2 and 12 have been canceled and claims 13-14 have been added.
  2. Claim 10 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction (election) requirement in Paper No. 13.
- NOTE:** Claims 5-6 and 11 are also withdrawn as being not included in the restriction requirement as directed to non-statutory subject matter (see restriction requirement).
3. Claims 1, 3-4, 7, 8-9, and 13-14 are under examination.
  4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
  5. The following Office Action contains some NEW GROUNDS of rejection.

### ***Rejections Withdrawn***

6. The rejection of claims 1-4, 7-9, and 12 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the amendments to the claims.
7. The rejection of claims 4, 7-9 and 12 under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description is withdrawn in view of the declaration filed by Roxane Demoncour.

8. The rejection of claims 1-3, 7-8 and 12 under 35 U.S.C. 103(a) as being unpatentable over Parker et al (Molecular and Cellular Biology 16:2561-2569, 1996, IDS #8) and further in view of Schaffhausen (Hybridoma Technology in the Biosciences and Medicine, PTO892, attach to #12) and Harlow et al (Antibodies, a laboratory manual, Cold spring harbor laboratory, chapter 6 and 7, 1988) and as evidenced from the specification is withdrawn in view of arguments.

9. The rejection of claims 1-3, 7-8 and 12 under 35 U.S.C. 103(a) as being unpatentable over Duchesne et al (US Patent 5,886,150, 7/97) and further in view of Schaffhausen (Hybridoma Technology in the Biosciences and Medicine, PTO892, attach to #12) and as evidenced from the specification is withdrawn in view of arguments.

***The Following is a NEW GROUND of rejection***

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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11. Claims 1, 3, 7, 8, 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a monoclonal antibody that binds an epitope between residues 22 to 34 of SEQ ID NO:1 and capable of inducing apoptosis in tumor cells and pharmaceutical compositions comprising such, does not reasonably provide enablement for a monoclonal antibody that binds to just any residues of 1 to 144 or 1 to 72 or 22 to 55 of SEQ ID NO:1 and capable of inducing apoptosis in tumor cells and pharmaceutical compositions comprising such. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The claims are broadly drawn to a monoclonal antibody that binds to just any residues 1-144, 1-72, 22-55 of SEQ ID NO:1 and is capable of inducing apoptosis in tumor cells. The specification only teaches one antibody, 1F1 1D1 that binds to an epitope of 22-34 of SEQ ID NO:1 and induces apoptosis in tumor cells (see example 4-5 and 7). The specification does not teach any other antibody directed to any other epitope in SEQ ID NO:1 with the properties of inducing apoptosis.

The prior art teaches that not all antibodies that bind to a tumor antigen are capable of inducing apoptosis. Ashkenazi et al (US Patent 6,252,050, 6/2001) teaches that only one antibody 3H3.14.5 had apoptotic activity out of the three that bound Apo-2 (see table 3). In addition, Arakawa et al teach that mAb74 has a distinct epitope from other anti-Her2 antibodies and this antibody induced apoptosis and the epitope is distinct from other antibodies that do not induce apoptosis and the region of Her2 which interacts with the antibody is important in eliciting an apoptotic response (see column 3, lines 5-10). Moreover, Arkawa et al (US Patent 5,783,186, 7/1998) teach that one antibody mab74 induced apoptosis and another mAb83 was only moderately active (see column 4). Thus, the prior art teaches that not all regions of a protein can be used to elicit apoptotic antibodies and in fact only certain epitopes can. Thus, one skill in the art would not predict that regions outside 22-34 of SEQ ID NO:1 would be capable of producing apoptotic antibodies as evidenced from the prior art that indicated only specific epitopes of the antibodies are capable of inducing apoptosis.

Therefore, in view of the lack of guidance in the specification and in view of the discussion above one of skill in the art would be required to perform undue experimentation in order to practice the claimed invention.

### ***Conclusion***

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12. Claims 4, 9, are in condition for allowance. Claim 14 is objected to as depending on a rejected claim but would be allowable if rewritten in independent form (i.e. not depending from claim 13 or 3).


13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571) 272-0871.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

Respectfully,

Larry R. Helms Ph.D.

571-272-0832



LARRY R. HELMS, PH.D  
PRIMARY EXAMINER